IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Alan K. Schaer
Application No. 10/805,738
Filed: March 22, 2004
Art Unit: 3742
Examiner: Quang T. Van

Title: Catheter Positioning System

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BRIEF ON APPEAL BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

This appeal arises from the Examiner's Final Rejection dated June 2, 2006 of claims 1-15.

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(i) Real Party in Interest

The real party in interest is Atrionix, Inc. as the assignee of the invention according to an assignment dated November 27, 2000 recorded at reel no. 015130 and frame no. 0148. Johnson & Johnson is the ultimate parent company of Atrionix, Inc.

(ii) Related Appeals and Interferences

To the best knowledge of the legal representative of assignee, Atrionix, Inc. and Johnson & Johnson, there are no other appeals or interferences that will directly affect or be affected or have a bearing on the Board's decision in the pending appeal.

(iii) Status of Claims

In the present Application Serial No. 10/805,738, claims 1-15 are at issue. Originally, fifteen claims were filed with the application on March 22, 2004. Claim 1 was amended on March 17, 2005. A further amendment to claim 1 was made along with a Request for Continuing Examination on August 22, 2005. Claim 1 was last amended on March 28, 2006 in response to a non-final Office Action. All dependent claims remain unchanged. The rejection of claims 1-15 is being appealed.

Claims 1-15 were filed with the application on March 22, 2004. In a first Office Action dated December 13, 2004, the Examiner rejected claims 1-2, 4, 6-8 and 12-13 under 35 U.S.C. § 102(e) as being anticipated by United States Patent No. 5,971,983 to Lesh ("Lesh"). Claims 1-7 and 10-15 were additionally rejected as being anticipated by United States Patent No. 6,332,880 to Yang ("Yang '880"). Claim 9 was rejected under 35 U.S.C. § 103 as being obvious over Lesh in view of United States Patent No. 6,237,605 to Vaska.

By a Response dated March 14, 2005, the Applicants amended claim 1 to include "a guiding introducer slidable within the transeptal sheath" and to clarify that the deflectable catheter is advanced through the guiding introducer.

The Examiner mailed a first Final Rejection on April 22, 2005 that reiterated the rejection of claims 1-7 and 10-15 based on Yang '880 and rejected claim 8 as being obvious over Yang '880 in view of Lesh. Claim 9 was rejected as being obvious over Yang '880 in view of Yaska.

Applicants filed a Request for Continuing Examination on August 22, 2005 and amended claim 1 therewith to recite that the claimed guiding introducer is "pre-shaped" so as to "direct the catheter toward the pulmonary vein.

A first Office Action after the RCE was issued by the Examiner on October 17, 2005 and reiterated the rejection of claims 1-7 and 10-15 as being anticipated by Yang '880. Claims 8 and 9 were rejected for the same reason stated in the previous paragraph. The Examiner considered the Applicants argument that Yang '880 fails to disclose a pre-shaped guiding introducer stating that "[t]he sheath (26) is a tubular shape which is a pre-shaped tube. . . ."

The Applicants responded by an amendment dated March 17, 2006 amending claim 1 to more distinctly point out and distinguish the claimed invention from Yang. The claims were amended to state that the guiding introducer is "preshaped to direct the catheter towards the pulmonary vein and the catheter is further directed into the pulmonary vein by manipulation of the pullwire along the proximal end portion."

By the second Final Office Action dated June 2, 2006, the Examiner rejected claims 1-7 and 10-15 under 35 U.S.C. § 103(a) as being obvious over Yang '880 in view of United States Patent No. 6,097,976 ("Yang '976"). Claims 8 and 9 were rejected as

obvious in view of Yang '880 and Yang '976 further in view of Lesh and Yaska respectively. This is the Office Action from which this appeal has been taken.

(iv) Status of Amendments

No amendments have been made or presented with respect to claims 1-15 after the final rejection of the Examiner on June 2, 2006 from which this appeal has been taken.

(v) Summary of Claimed Subject Matter

The presently claimed invention relates to a positioning system adapted to guide a medical device, preferably an ablation element, to a location where a pulmonary vein extends from an atrium. The positioning system includes a transeptal sheath **82** [¶0145-¶1048, FIGS. 6-8] inserted through an atrial septum that separates the right atrium from the left atrium in the heart. The system further includes a guiding introducer **10** [¶0063-¶0068, FIG. 1-3 and ¶145-147, FIGS. 6-7] slideably engaged within the transeptal sheath that has a preshaped distal portion adapted to direct the medical device (such as ablation element **110** [FIG. 7] toward the pulmonary vein. The positioning system also includes a torqueable and steerable deflectable catheter **94** [¶0146-¶0149, FIGS. 7-8] on which the medical device is disposed. A pullwire in the deflectable catheter deflects the distal end of the catheter so that the catheter and the medical device thereon can be advanced through the guiding introducer that is pre-shaped in order to direct the catheter toward and into the pulmonary vein [¶ 146-148, FIG.7]. In dependent claims 8-12, the ablation element comprises a microwave ablation element [¶0090], a cryogenic ablation element [¶0031], a thermal ablation element [¶0090], a light-emitting ablation element [¶0090] and an ultrasound transducer [¶0167] respectively.

(vi) Grounds of Rejection to be Reviewed on Appeal

By the second Final Office Action dated June 2, 2006, the Examiner rejected claims 1-7 and 10-15 under 35 U.S.C. § 103(a) as being obvious over Yang '880 in view of United States Patent No. 6,097,976 ("Yang '976"). Claims 8 and 9 were rejected as obvious in view of Yang '880 and Yang '976 further in view of Lesh and Yaska respectively.

More specifically, the Examiner held that the Yang '880 patent discloses in FIG. 11, "a catheter assembly [having] a transeptal sheath (74); a guiding introducer (26) slidable within the transeptal sheath (74); a deflectable catheter (12) having a proximal (14) and distal end (16) portions, wherein the deflectable catheter (12) is configured to be torqueable and steerable (col. 1, lines 25-45); and a pullwire (32) integrated within the deflectable catheter (12) that is adapted to deflect at least a portion of the distal end (16) portion such that the deflectable catheter (12) may be advanced through the guiding introducer (26) wherein the guiding introducer (26) directs catheter (12) towards the pulmonary vein and the catheter (12) is further directed into the pulmonary vein by manipulation of the proximal end portion (14)."

The Examiner admits that the Yang '880 reference does not disclose a guiding introducer that is pre-shaped to direct the catheter. The Examiner cites the Yang '976 reference as teaching a pre-shaped guiding catheter that can be combined with the teaching of Yang '880 to arrive at the claimed invention.

The subject matter in dependent claims 2-7 and 10-15 was not specifically addressed by the Examiner.

The Examiner rejected claim 8 as being unpatentable over the two Yang references further in view of Lesh (U.S. Patent No. 5,971,983). The Examiner admits that the Yang references do not teach or suggest the use of a microwave ablation element. The Examiner states that it would be obvious to combine the two Yang references with the microwave ablation element disclosed at col. 9, lines 43-60 of Lesh to arrive at the invention of claim 8.

The Examiner rejected claim 9 as being unpatentable over the two Yang references further in view of Yaska (U.S. Patent No. 6,237,605). The Examiner admits that the Yang references do not teach or suggest the use of a cryogenic ablation element and cites Yaska for this teaching. The Examiner states that it would have been obvious to one skilled in the art at the time the invention was made to utilize the cryogenic ablation element of Vaska in a system based on the combined teachings of the Yang references.

The issues presented this appeal are:

I. Whether claims 1-7 and 10-15 would have been obvious to one skilled in the art at the time of the invention in over United States Patent No. 6,332,880 ("Yang '880") in view of United States Patent No. 6,097,976 ("Yang '976").

II. Whether claim 8 would have been obvious to one skilled in the art at the time of the invention over United States Patent No. 6,332,880 ("Yang '880") and United States Patent No. 6,097,976 ("Yang '976") in view of United States Patent No. 5,971,983 ("Lesh").

III. Whether claim 9 would have been obvious to one skilled in the art at the time of the invention over United States Patent No. 6,332,880 ("Yang '880") and United States Patent No. 6,097,976 ("Yang '976") in view of United States Patent No. 6,237,605 ("Yaska").

(vii) Argument

I. Rejection of Claims 1-7 and 10-15 under 35 U.S.C. § 103(a) over Yang '880 in view of Yang '976 was improper

Claims 1-7 and 13-15

Applicants submit that claims 1-7 and 13-15 would not have been obvious to one skilled in the art at the time of the invention. The Examiner has admitted that the Yang '880 reference fails to disclose a guiding introducer that is pre-shaped so as to direct the catheter. Applicants submit that this is only one of the failings of the Yang '880 reference and these failings are not overcome by the Yang '976 reference.

The Examiner points to sheath 74 of Yang '880 as being the transeptal sheath of the present invention. In the cited FIG. 11 of Yang, "a sheath 74 slides (arrows 76) along the exterior of the catheter body 14 between a forward position overlying the wire 72 (FIG. 12) and an aft position away from the wire 72 (FIG. 11). In its forward position, the sheath 74 retains the distal catheter end 16 in a straightened configuration against the normal bias of the wire 72, as FIG. 12 shows. The sheath 74 may include spirally or helically wound fibers to provide enhanced torsional stiffness to the sheath 74. Upon movement of the sheath 74 to its aft position, as FIG. 11 shows, the distal catheter end 16 yields to the wire 72 and assumes its normally biased bent position. The slidable sheath 74 carries a suitable gripping surface (not shown), like the gripping surface 36 of the sheath 26, to affect forward and aft movement of the sheath 74 for the purposes described." (Yang '880, col. 12, lines 3 – 17).

The Examiner posits that the second flexible sheath (26) of Yang '880 is equivalent to the claimed guiding introducer although the Examiner does acknowledge that sheath (26) is not pre-shaped to direct the catheter toward the pulmonary vein.

The Examiner then cites column 2, lines 62-67 of the Yang '976 reference as disclosing such a pre-shaped catheter. This section of the Yang '976 reference is set forth below:

> "Further, if the catheter is introduced through a close-fitting introducer (e.g., such as a pre-shaped guide sheath), the regenerated cellulose coating can become stretched axially relative to the underlying catheter body structure. Because there is no conductive fluid such as saline between the electrode and regenerated cellulose coating, the electrical path, can become intermittent or open where the two materials become separated." (Yang '976, col. 2, line 62 to col. 3, line 2).

Other than containing the term "pre-shaped" this passage does not teach or suggest any type of guiding introducer that is pre-shaped to direct a catheter toward a pulmonary vein. Further there is no disclosure in the Yang '976 reference as to what is meant by "pre-shaped." None of the drawings show any type of guiding introducer let

alone one that is pre-shaped to direct a catheter to a pulmonary vein. Furthermore, there is no teaching or suggestion in the Yang '976 reference that the "pre-shaped guide sheath" is slidable within a transeptal sheath.

Applicants submit that the reference does contain the correct "key-word" but does not overcome the deficiency of the primary reference. There is no teaching or suggestion in either Yang reference that would lead to the claimed invention, i.e., a positioning system having a transeptal sheath, a guiding introducer slidable within the transeptal sheath and a deflectable catheter having a pullwire wherein the guiding introducer is pre-shaped in order to direct the catheter towards the pulmonary vein and the catheter is further directed into that vein by manipulation of a pullwire.

Furthermore, the Examiner has cited element 32 of FIG. 11 of the Yang '880 reference as being a pullwire. Element 32 is an elliptical sleeve. "Elliptical sleeve 32 will rotate until it contacts the butterfly shaped keyway within sheath 26. The prescribed range allows the loop structure 20 to be flipped over upon itself . . . ." (col. 12, lines 34 – 36). This does not teach or suggest the use of a pullwire to deflect at least a portion of the distal end portion of the deflectable catheter in order to direct the catheter toward and into the pulmonary vein. The Yang '880 reference is primarily concerned with implementing an ablation loop from a straight element by bending a catheter to form a loop wherein a flexible joint 44 is formed from a portion or "remnant" of the sheath 26. The Yang '880 reference is not concerned with directing a catheter into the pulmonary vein. Likewise, the Yang '976 patent is not concerned with this issue. The Yang '976 patent is directed to surface coatings on the distal ends of catheters.

Additionally, Applicants submit that there would be no motivation to combine the Yang references even if the Yang '976 patent taught a guiding introducer that is pre-shaped to direct the catheter to the pulmonary vein. Neither reference suggests the combination of a transeptal sheath, the guiding introducer and the deflectable catheter having a pullwire.

Claim 10

Applicants submit that neither Yang reference teaches or suggests the positioning system of claim 1 and further neither teaches nor suggests the use of a thermal ablation system of claim 10. The Yang '880 reference teaches the use of RF ablation but does not discuss thermal ablation. The Examiner did not cite any passage in either Yang reference that discusses thermal ablation.

Claim 11

Applicants submit that neither Yang reference teaches or suggests the positioning system of claim 1 and further neither teaches nor suggests the use of a light-emitting ablation system of claim 11. The Yang '880 reference teaches the use of RF ablation but does not discuss light-emitting ablation. The Examiner did not cite any passage in either Yang reference that discusses light emitting ablation.

Claim 12

Applicants submit that neither Yang reference teaches or suggests the positioning system of claim 1 and further neither teaches nor suggests the use of an ultrasound transducer as an ablation element as in claim 12. The Yang '880 reference teaches the use of RF ablation but does not discuss ultrasonic ablation. The Examiner did not cite any passage in either Yang reference that discusses ultrasound ablation.

II. Rejection of Claims 8 under 35 U.S.C. § 103(a)
over Yang '880 in view of Yang '976 further in view of Lesh

Claim 8 should be allowed for the reasons stated above with respect to claim 1. Furthermore, Applicants submit that the combination of three references, Yang '880, Yang '976 and Lesh would not have been obvious to one skilled in the art. Lesh does not overcome the deficiencies of the primary and secondary references. Lesh does discuss the use of an antenna that would be energized by microwave energy but does not teach or suggest the positioning system of claim 1. Furthermore, there is no teaching or suggestion in any of the references that would lead one skilled in the art to combine all three references into the invention of claim 8.

III. Rejection of Claim 9 under 35 U.S.C. § 103(a)
over Yang '880 in view of Yang '976 further in view of Vaska

Claim 9 should be allowed for the reasons stated above with respect to claim 1. Furthermore, Applicants submit that the combination of three references, Yang '880, Yang '976 and Yaska would not have been obvious to one skilled in the art. Yaska does not overcome the deficiencies of the primary and secondary references. Yaska does briefly discuss the use of a cryogenic ablation element but does not teach or suggest the positioning system of claim 1. Furthermore, there is no teaching or suggestion in any of the references that would lead one skilled in the art to combine all three references into the invention of claim 9.

Conclusion

Appellant's inventive positioning system contains novel and non-obvious features that are neither taught nor suggested by the cited Yang references either alone or in combination. For the reasons set forth above, Applicants submit that the Final Rejection of claim 1-15 is in error. Reversal of this rejection, therefore, is respectfully requested.

Respectfully submitted,

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(viii) Claims Appendix

Claim 1 (previously amended): A positioning system for guiding a medical device to a location where a pulmonary vein extends from an atrium, comprising:

a transeptal sheath;

a guiding introducer slidable within the transeptal sheath;

a deflectable catheter having proximal and distal end portions, wherein the medical device is disposed along the distal end portion, and wherein the deflectable catheter is configured to be torquable and steerable; and

a pullwire integrated within the deflectable catheter that is adapted to deflect at least a portion of the distal end portion such that the deflectable catheter may be advanced through the guiding introducer wherein the guiding introducer is pre-shaped to direct the catheter towards the pulmonary vein and the catheter is further directed into the pulmonary vein by manipulation of the pullwire along the proximal end portion.

Claim 2 (original): The positioning system of claim 1, wherein the medical device further comprises an electrode element.

Claim 3 (original): The positioning system of claim 2, wherein the electrode element comprises a mapping electrode.

Claim 4 (original): The positioning system of claim 2, wherein the electrode element comprises an ablation electrode.

Claim 5 (original): The positioning system of claim 2, wherein the electrode element comprises both a mapping electrode and an ablation electrode.

Claim 6 (original): The positioning system of claim 2, wherein the electrode element is an RF ablation element.

Claim 7 (original): The positioning system of claim 1, wherein the medical device further comprises an ablation element.

Claim 8 (original): The positioning system of claim 6, wherein the ablation element comprises a microwave ablation element.

Claim 9 (original): The positioning system of claim 6, wherein the ablation element comprises a cryogenic ablation element.

Claim 10 (original): The positioning system of claim 6, wherein the ablation element comprises a thermal ablation element.

Claim 11 (original): The positioning system of claim 6, wherein the ablation element comprises a light-emitting ablation element.

Claim 12 (original): The positioning system of claim 6, wherein the ablation element comprises an ultrasound transducer.

Claim 13 (original): The positioning system of claim 6, wherein the ablation element is adapted to form a linear lesion.

Claim 14 (original): The positioning system of claim 6, wherein the ablation element is adapted to form a circumferential lesion.

Claim 15 (original): The positioning system of claim 14, wherein the ablation element is adapted to form the circumferential lesion at the location.

(ix) Evidence Appendix

None.

(x) Related Proceedings Appendix

None.